



REMARKS

No claims have been canceled, amended, or added. Accordingly, after entry of this Amendment, claims 1-62 will remain pending.

In the Office Action, the Examiner rejected claims 1-62 under the judicially-created doctrine of obviousness-type double patenting. The Examiner suggested filing a Terminal Disclaimer to overcome the rejection.

The Applicant respectfully traverses the Examiner's rejection under this doctrine as a *prima facie* case of obviousness has not been presented. Nevertheless, to expedite examination of this application, the Applicant submits herewith a Terminal Disclaimer.

In the Office Action, the Examiner rejected claims 1-7, 22, and 24 under 35 U.S.C. § 103(a) as unpatentable over Saini et al. (an article entitled "In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media") in view of Boyd (U.S. Patent No. 4,613,328). The Applicant respectfully disagrees with the Examiner's rejection and, accordingly, traverses same.

Saini et al. describes an injector apparatus for use with a Magnetic Resonance ("MR") imager. In particular, Saini et al. describes the apparatus as follows:

*Injector Hardware*

A commercially produced mechanical injector used for contrast infusion in angiography and computed tomography (CT) (Mark V; Medrad, Pittsburgh, PA) was modified and installed in a clinical MR imager (0.6-T Teslacon superconducting magnet; Technicare, Solon, OH). The components of the MR injector consisted of a main unit, control panel, drive unit, and injector head. The main unit contained the electronics of the system and was mounted in a corner of the radiofrequency (RF)-shielded room. Controls necessary to program, activate, and monitor an infusion were on the control panel. For convenience, this panel was mounted adjacent to the MR scanner's operating console. The control panel and main unit were connected with an interface cable. The drive unit containing a mechanical motor was embedded in a concrete block and placed at the foot of the patient table. The motor was connected to an AC outlet (110 V, 60 Hz, or 220 V,

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50 Hz) and the main panel with electrical cables. The injector head was tailored for a magnetic environment by substituting standard components with nonferromagnetic materials. It was located adjacent to the MR scanner's aperture and was mounted such that it could be pointed in any direction. A disposable 65-mL syringe was placed in the injector head for contrast infusion. The mechanical motor and injector head were connected with an electrical cable and a flexible drive shaft.

Saini et al. at page 748. As the Examiner pointed out, there is nothing in Saini et al. that describes or suggests the use of a battery for powering the motor control circuitry and the electric drive motor and for minimizing electromagnetic interference with the magnetic resonance imaging apparatus.

Contrary to the Examiner's assertion, Boyd cannot be combined properly with Saini et al., because Boyd describes an apparatus antithetical to the construction of the Saini et al. apparatus. Boyd describes an electrically-powered hypodermic needle. In Boyd's apparatus 10, the motor drive 28, solenoid 32, control assembly (or "brain") 38, and needle 24 are all housed within a single base means 12. (Boyd at Fig. 1.) In the embodiment illustrated in Fig. 1, the power supply 14 (a "transformer circuit plugged directly into the usual wall socket" (Boyd at col. 4, lines 12-13)) is separate from the base means 12. While not illustrated, if the Boyd apparatus 10 included a rechargeable battery as a power source, the rechargeable battery must, by necessity, also be accommodated in the same base means 12. Therefore, in the case where Boyd's hypodermic needle is battery powered, all of the components would have to be contained within a single housing.

As the Applicant pointed out, one of the objects of the present invention is "to provide an MRI system which minimizes the interference between fields created by the electric motors used to drive the contrast media injection plungers and the magnetic field used to generate the magnetic field resonance image." (The specification (the '036 patent) at col. 2, lines 21-25.) Because spurious radiation can be created when electrical lines are placed under the floor or through the walls of a shielded room, another object of the invention is to

eliminate, to the extent possible, any such electrical lines or cables. (See the specification at col. 1, lines 31-57, and at col. 2, lines 15-20.) Incorporating a battery 32 in the injection control unit 30 advantageously assists in accomplishing this objective.

Given these objectives, there are at least two difficulties with the combination of Boyd and Saini et al. First, since Boyd teaches an integral injector apparatus, its teachings, as outlined above, are inconsistent with (and, in fact, antithetical to) the teachings of Saini et al., which requires that the various components be separated from one another. As a result, in trying to use the references in conjunction with one another, an immediate question arises as to how they may be combined. Second, there is nothing in Boyd to suggest that the battery be connected to a particular subcomponent of the apparatus. As a result, there is nothing in Boyd to suggest that a battery be connected to the motor control circuitry described in Saini et al. Because Boyd teaches that the components are combined within a single housing 12, it may be inferred that the battery could be coupled to any of the subcomponents of the apparatus 10. In other words, applying the teaching of Boyd to Saini et al., it is equally likely that one of ordinary skill in the art would think to combine the battery with other subcomponents (such as the system controller or injector head control unit). Connection to the contrast media controller is not the only logical result.

At least for these reasons, therefore, the Applicant respectfully submits that Saini et al cannot be properly combined with Boyd to render claims 1-7, 22, and 24 obvious. Accordingly, the Applicant respectfully requests that the Examiner withdraw the rejection of those claims.

In the Office Action, the Examiner also rejected claims 8-16, 18-20, 21, and 23 under 35 U.S.C. § 103(a) as unpatentable over Saini et al. in view of Sugahara (U.S. Patent No. 5,464,014). The Applicant respectfully disagrees with the Examiner's rejection and, therefore, traverses same.

The discussion of Saini et al., above, applies equally here. The Applicant respectfully submits that that Sugahara cannot be properly combined with Saini et al. to render obvious the present invention because Sugahara does not describe any fiber optic communications link between the system controller and the infusion apparatus control means. The Examiner has not identified anything within Sugahara (and there is nothing in Sugahara that the Examiner could rely on) that would suggest such a combination.

Sugahara describes a display device for bioelectrical and biophysical phenomena. Specifically, Sugahara is directed to the placement of a display device 10 within the MRI booth (the room containing the MR imager) that permits the physician to keep “constant tabs on the physiological condition of the patient” while the physician is in the MRI booth. (Sugahara at col. 4, lines 13-14.) The entirety of the disclosure of Sugahara concerns how to minimize the electromagnetic (“EM”) impact of the placement of such a display 10 and its associated electrical cabling within the MRI booth.

The Applicant concedes that Sugahara does discuss the potential for using optic communications between the display 10 and the display monitor 7 within the control room. Specifically, Sugahara states:

Moreover, the transmission need not be limited to electric signals and a light signal carrier may be modulated with an ECG or blood pressure and other signals transmitted to the display device 10 via a fiber optic cable.

The magnetic-shielded cable and fiber cable have been referred to in the foregoing description but a light transmission system which does not require wiring may be employed. For example, since a window for monitoring the patient is available between the MRI booth and the control room, a light transmitter and a light receiver may be juxtaposed across the window for the transmission and reception of ECG and blood pressure and other signals. The light signal carriers which can be used for this purpose may be infrared rays or laser beams. Since this communication system does not produce an electric noise, there will be no adverse effect on the MRI unit.

(Sugahara at col. 6, lines 47-62.) As indicated above, however, the Applicant contests that there is no suggestion in Sugahara for any fiber optic communications link between the system controller and the infusion apparatus control means.

Were Sugahara combined with Saini et al., one of ordinary skill in the art would create an injector system in an MRI booth, where the MRI booth includes a display optically connected to the control room. However, that person of ordinary skill would not arrive at the claimed invention. Accordingly, the Applicant respectfully requests that the Examiner withdraw the rejection of claims 8-16, 18-20, 21, and 23.

In the Office Action, the Examiner also rejected claims 17, 25-32, 34-51, and 53-61 under 35 U.S.C. § 103(a) as unpatentable over Saini et al. in view of Sugahara, and further in view of Boyd. As with the previous rejections, the Applicant respectfully disagrees with the Examiner's rejection and, therefore, respectfully traverses same. The Applicant points out that claim 17 depends from claim 13 and adds, *inter alia*, a rechargeable battery to the claimed apparatus. The discussions of Saini et al., Sugahara, and Boyd apply to these claims for the same reasons stated above.

In particular, the Applicant respectfully submits that, at least for the same reasons that Boyd cannot be properly combined with Saini et al. to render claims 1-7, 22, and 24 obvious, Boyd cannot be properly combined with both Saini et al. and Sugahara to render claims 17, 25-32, 34-51, and 53-61 unpatentable. Accordingly, the Applicant respectfully requests that the Examiner withdraw the rejection of claims 17, 25-32, 34-51, and 53-61.

Finally, the Examiner rejected claims 33, 52, and 62 under 35 U.S.C. § 103(a) as unpatentable over Saini et al. in view of Sugahara, and further in view of Reilley et al. (U.S. Patent No. 4,677,980). As with the rejections addressed by the Applicant above, the Applicant respectfully disagrees with this rejection and, therefore, respectfully traverses same.

The discussions of Saini et al. and Sugahara above apply equally here. Applicant respectfully submits that, at least for the same reasons that Sugahara cannot be properly combined with Saini et al. to render claims 8-16, 18-20, 21, and 23 obvious, Sugahara cannot be properly combined with both Saini et al. to render claims 33, 52, and 62 unpatentable. Accordingly, the Applicant respectfully requests that the Examiner withdraw the rejection of claims 33, 52, and 62.

In addition, the Applicant respectfully points out that Reilley et al. generally describes an angiographic injector and angiographic syringe for use therewith. In particular, Reilley et al. describes an angiographic injector 10 with a turret 14 rotatably mounted around shaft 61. (Reilley et al. at col. 3, lines 25-30.) Two pressure jackets 16 and 16a are fixed in the turret 14 and house respective syringe cartridges 18 and 18a. (Reilley et al. at col. 3, lines 34-36.) The turret 14 houses the syringe cartridges 18 and 18a so that the syringe 18 in pressure jacket 16 is in readiness for injection. (Reilley et al. at col. 1, line 64, to col. 2, line 1.) This permits rapid replacement of one syringe for the other. For example, after the syringe 18a is emptied, the syringe 18 may be quickly moved into position to continue the medical diagnostic procedure. In Reilley et al., the contents of only one syringe may be injected at any given time.

In contrast, the present invention describes an injector that is adapted to accommodate at least two syringes mounted thereon. The two injection syringe and piston units 40, 42 are each connected to a respective electric motor by flexible drive shafts 44, 46, which suggests that both syringes may be employed at the same time. Since Reilley et al. does not describe or suggest such a construction, it cannot be properly combined with Saini et al. and Sugahara to render claims 33, 52, and 62 obvious. Accordingly, the Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 103(a).



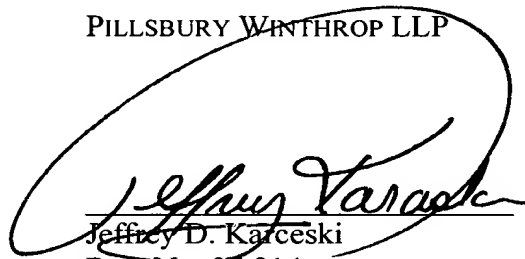
Uber, III et al. - Serial No. 09/545,582 - Atty. Dkt. No. 071419/0272813

In view of the foregoing, the Applicant respectfully submits that claims 1-62 are patentable. Accordingly, the Applicant respectfully requests that the Examiner withdraw the rejections and pass this application quickly to issue.

If there are any fees required for the submission of this Amendment that are not otherwise accounted for, please charge our Deposit Account No. 09-3975 and refer to Invoice No. 071419/0272813.

Respectfully submitted,

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**APPENDIX**  
**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE SPECIFICATION:**

**The specification is changed as follows:**

**Page 1, before line 1, as a new full paragraph as follows:**

This application is a continuation of United States Reissue Patent Application Serial  
No. 09/027,852, which is now Re. 36,648.

**END OF APPENDIX**

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